Industry Coalition on 21 CFR Part 11

Advanced Medical Technology Association
America's Blood Centers
Animal Health Institute
Biotechnology Industry Organization
Consumer Healthcare Products Association
Cosmetic, Toiletry, and Fragrance Association
Council for Responsible Nutrition
Council on Radionuclides and Radiopharmaceuticals
Generic Pharmaceutical Association
Medical Device Manufacturers Association
National Electrical Manufacturers Association
National Food Processors Association
Pharmaceutical Research and Manufacturers of America

November 22, 2002

Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket Number 00D-1540; Draft Guidance for Industry on Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records; 67 Federal Register 68674; **Request to Withdraw the Guidance**

Dear Sir or Madam:

The Industry Coalition on 21 CFR Part 11 composed of the above noted trade associations requests that FDA withdraw the Draft Guidance for Industry on Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records. This Draft Guidance, issued on November 12, 2002, may no longer be representative of the FDA's current thinking on issues pertaining to electronic copies of electronic records.

In late August the FDA announced an initiative to enhance pharmaceutical Good Manufacturing Practices (GMPs). As part of this initiative, the Agency shifted the lead on implementation of Part 11 to Center for Drug Evaluation and Research (CDER), with continued involvement from the other Centers and the Office of Regulatory Affairs. It is expected that as part of this initiative that emerging science and data analysis will be used to enhance compliance programs to target the highest risk areas. Since this will refocus Agency thinking on a number of the aspects of Part 11 compliance, all draft Guidance documents issued to date will need to be significantly revised.

The Industry Coalition has exerted considerable effort in responding to the previous draft Guidance on Part 11. As this draft Guidance was prepared prior to the Agency's announcement of the new GMP initiative, commenters may spend significant effort addressing issues that are no longer relevant to the FDA's new approach to this regulatory issue. The Industry Coalition believes that all parties will be best served by withdrawing this guidance and that any future draft Guidance publication await an FDA policy statement on the direction of the scope of Part 11 compliance activities.

00D-1540 C1

The Industry Coalition thanks the FDA for considering this request and stands ready to respond to any questions.

Sincerely,

Alan Goldhammer, PhD
Associate Vice President for
Regulatory Affairs
Pharmaceutical Research and
Manufacturers of America, and
Chair of the Industry Coalition on 21 CFR Part 11

Cc: Janet Woodcock, MD, CDER
Joseph Famulare, CDER